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10/566,588	03/09/2006	Taro Yoshikawa	126835	7199
25944 7590 08/18/2010 OLIFF & BERRIDGE, PLC P.O. BOX 320850 ALEXANDRIA, VA 22320-4850				
EXAMINER				
LAU, JONATHAN S				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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ADVISORY ACTION

The proposed amendments AFTER FINAL, filed 30 July 2010, will be entered because they require only a cursory review by the examiner.

Continuation of 11. Applicant's Remarks, filed 30 July 2010, have been fully considered and found not to be persuasive.

The proposed amendments AFTER FINAL, filed 30 July 2010, will be entered, and the amended claims are considered herein.

With regard to the limitation wherein the glycyrrhizin, cysteine and aminoacetic acid are dissolved in water, Van Rossum et al. teaches Stronger Neo Minophagen C, a solution for intravenous use comprising of 2 mg/mL glycyrrhizin, 1 mg/mL cysteine, and 20 mg/mL glycine in physiological saline (page 203, left column, paragraph 1 in section Clinical Investigations). It is well known that physiological saline is sodium chloride dissolved in water. The instant claims, reciting the open transitional phrase "containing", do not exclude the sodium chloride present in physiological saline. Therefore the teaching of Van Rossum et al. is encompassed within the instant claims wherein the glycyrrhizin, cysteine and aminoacetic acid are dissolved in water because Van Rossum et al. teaches 2 mg/mL glycyrrhizin, 1 mg/mL cysteine, and 20 mg/mL glycine plus sodium chloride dissolved in water, or 2 mg/mL glycyrrhizin, 1 mg/mL cysteine, and 20 mg/mL glycine dissolved in physiological saline.

Applicant again notes that Chen is drawn to a glycyrrhizin complexed with an active agent, not glycyrrhizin as a pharmaceutical agent in its own right. Applicant notes

that Chen teaches the active agent is a compound other than glycyrrhizin. However, as previously stated, the rejection is not made of Chen alone, and Van Rossum teaches glycyrrhizin having pharmaceutical activity (abstract) and at page 203, left column, paragraph 4 teaches the combination of glycyrrhizin with cysteine and glycine, where cysteine and glycine are taught to have pharmaceutical activity of their own. As previously stated, one of ordinary skill in the art would be motivated to increase the concentration glycyrrhizin because Van Rossum et al. teaches the composition administered at a dose of 80 mg glycyrrhizin daily and to increase the concentration of glycine and cysteine proportionately with the glycyrrhizin because Van Rossum et al. teaches glycine and cysteine play a physiological role along with glycyrrhizin. That Chen teaches an additional benefit of glycyrrhizin complexed with an active agent does not negate the teaching of Van Rossum et al.

Applicant notes that Mollica nowhere discloses that sulfites cause precipitation of glycyrrhizin, cysteine or aminoacetic acid. Applicant remarks that Mollica indicates that there is a high degree of uncertainty in the art as to the performance of a given type of additive with different compounds in view of the different reactions that may occur. Applicant contrasts this with the teaching of Van Rossum of successful use of a sulfite in a composition of glycyrrhizin, cysteine and aminoacetic acid at low concentration. Applicant remarks that in view of these teachings it would not have been obvious to one of ordinary skill in the art to eliminate sulfites. However, Mollica as cited as the level of ordinary skill in the art provides evidence that degree of uncertainty in the art as to the performance of a given type of additive with different compounds is expected by one of

ordinary skill in the art at the time of the invention. Therefore, one of ordinary skill in the art would have had a reasonable expectation of similar but not exactly identical properties for equivalents such as sodium benzoate, sorbic acid, propionic acid, acetic acid, nitride, nitrates and sulfites as taught by Chen to be preservatives known in the art.

Applicant again refers to evidence provided in the specification regarding improved stability and lack of glycyrrhizin precipitation. However, this is not persuasive because it is not commensurate with the scope of the claim, in that the claim recites substantially no sulfite is contained but is left open to the presence of other preservatives such as sodium benzoate, sorbic acid, propionic acid, acetic acid, nitride and nitrates are known in the art as equivalents of sulfites as taught by Chen. As recited above, and in view of the level of ordinary skill in the art with regard to the degree of expected uncertainty as to the performance of a given type of additive with different compounds, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute preservatives known for the same purpose. The claims only require substantially no sulfite, for example the specific stabilizer sodium sulfite (specification page 3, paragraph 3) but do not exclude any other stabilizer used as a stabilizer in the conventional product.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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